



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANAKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #28 syringes per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

If yes, **approve for 6 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

- A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) or Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)
- B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
 1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
 3. You have previously tried at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
 4. You have previously tried any **TWO** of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #28 syringes per 28 days.**

If no, continue to #2.

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RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

- A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) or Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)
- B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
 - 1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kineret.

REFERENCES

- Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); June 2018.

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Yes	Yes	No

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